Design of a Realistic Knee Model to Assess a Surgeon's Ability to Determine Knee Laxity during a Total Knee Arthroplasty

Undergraduate Thesis

Presented in Partial Fulfillment of the Requirements for graduation in the undergraduate colleges of The Ohio State University

By

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The Ohio State University
2017

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Abstract

A total knee arthroplasty (TKA) is a common end-stage treatment for knee osteoarthritis (OA), and affects millions in the US. A primary objective of a TKA is to reduce pain and improve function by providing the patient with a stable, balanced knee. To determine if the knee is stable and balanced, surgeons will often use a varus-valgus stress test to qualitatively determine if there are problems with knee laxity (how tight or loose the ligaments are) before and after a TKA. If the knee is too loose, too tight, or malaligned, the surgeon intra-operatively adjusts the soft tissues (e.g., ligaments) appropriately. However, these methods rely on a surgeon's experience and judgment to "feel" for normal knee laxity, which could lead to variability in the outcomes of TKAs. The purpose of this research was to design a realistic knee model the can be used to assess a surgeon's ability to determine knee laxity using the manual varus-valgus stress test. This was done by designing normal (intact ligaments and no diseased bone) model knees in flexion and extension based on literature and previously collected data from cadavers. These models were validated with a stability rig developed at Ohio State. Each knee was designed to be safe, repeatable and realistic in appearance and motion. Tests were performed on multiple prototypes, showing that a range of laxities could be achieved that align with trends from previous studies. The final models were compared literature, as well as to data previously collected on cadavers from the Neuromuscular Biomechanics Laboratory at Ohio State. The final extension model rotated about 2.75 degrees in varus (differed from data by 0.25 degrees) and 1.25 degrees valgus (differed from literature by 0.25 degrees) at 10 Nm. The flexion model differed from literature by about 0-1 degrees, but this model was not repeatable. These knee models can serve as a baseline for the future knee models with varying laxities that can be used test surgeons' ability to determine the laxity of the models.

The results of this test could validate the current procedure for a varus-valgus stress test, or could lead to the development of different training modules or devices that could help decrease the variability of TKAs.

Acknowledgements

I would like to thank Rachel Baker for giving me guidance throughout this project. She helped me learn a lot through the process and took a lot of time out of her day to help me. I would also like to thank Dr. Robert Siston. He encouraged me to participate in undergraduate research; I have learned a lot about the research process, and valuable skills that can be applied elsewhere, because of this. I would also like to thank the rest of the NMBL members for their willingness to answer my questions and helping me with testing the models. Lastly, I would like to thank Aaron and the student workers in the student machine shop for helping me machine some of the components for this project.

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1. Introduction

Between 2010-2012, 52.5 million adults had doctor-diagnosed osteoarthritis (OA) in the United States (US) [1]. Osteoarthritis is a painful disease that occurs when cartilage wears down and the bones come in contact with one another, and often occurs in the knee [2]. Symptoms of knee OA include physiological changes as well as functional deficits. Some physiological changes include malalignment in the leg, which is caused by cartilage breakdown, and changes in knee laxity [3, 4]. Knee OA causes joint pain and loss of function, which makes it difficult for a patient to perform daily activities [3].

Since knee OA is a common condition, total knee arthroplasties (TKAs) are a frequent end-stage surgical procedure [5]. Over 719,000 TKAs are implemented each year in the US, and this is projected to increase to 3.48 million in 2030 [6]. The objective of a TKA surgical procedure is to relieve pain and restore function by providing the patient with a stable, balanced knee. The surgeon will do this by correcting malalignment of the leg, placing the prosthetic components into their proper orientation, and balancing the soft tissues.

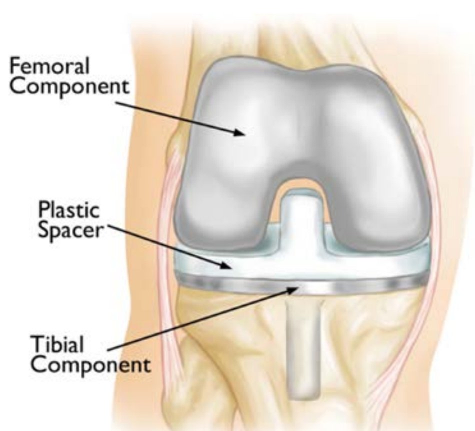


Figure 1: TKA Prosthetic Components with soft tissues
Source: http://orthoinfo.aaos.org/topic.cfm?topic=a00221

TKAs are generally one of the most successful orthopedic procedures [7]; however, suboptimal outcomes can occur. These suboptimal outcomes include limited range of motion and difficulty performing daily activities, with up to 50% of TKA patients having trouble climbing stairs after surgery [8]. There are many variables that can affect the outcome of a TKA, including patient variability and the alignment of the prosthetic components [9]; however, many complications after a TKA may be due to soft tissue balancing [10].

Soft tissue balancing is an important factor for a successful TKA [9]. The objective of soft tissue balancing is to restore alignment in the leg, while still giving the patient a stable knee [10, 11]. Ligament balancing consists of adjusting the collateral ligaments until the knee laxity feels normal in varus (tibia rotating inward toward the midline of the body) and valgus (tibia rotating away from the midline of the body) (Figure 2). Balancing the ligaments helps to reduce wear and loosening of the prosthetic joint, and patients with balanced knees are more likely to have an increased range of motion and decreased pain [12]. Various techniques have been developed in order to intra-operatively assess the soft tissues appropriately to try to provide the patient with a stable knee [13, 14]. Regardless of technique, it is assumed that equal flexion and extension gaps create this stable knee (Figure 3) [15]. Surgeons try to balance tissues to provide a patient with a knee that is neither “tight” nor “loose”, but no objective data defines how much “tightness” or “looseness” is required in order for a successful TKA [9]. If adjusting the soft tissue causes the knee to be too loose, this could cause instability and loosening of the prosthetic joint, which could ultimately lead to failure of the knee replacement [9, 16]. However, if the knee is too tight, this could cause a limited range of motion in the knee [16]. Having a limited range of motion could be uncomfortable for the patient and could make it difficult for patients to perform daily activities. Surgeons rely on qualitatively determining “tightness” or “looseness” and adjust the soft tissue based on their “feel”. Failing to properly adjust the soft tissues can lead to complications after the surgery, which can lead to suboptimal outcomes, such as functional deficits, instability or even revision surgery [9]. 9% of all TKAs are for a revision (i.e., repeated surgery), and nearly half of these surgeries may be prevented with correct ligament balancing [12].

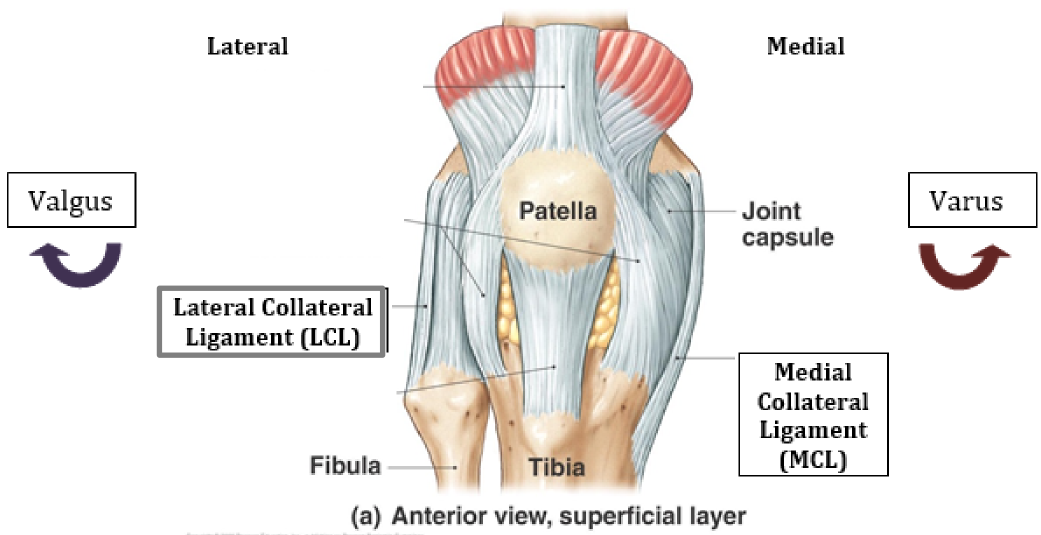


Figure 2: Knee Ligaments and Soft Tissue in a right knee
Source: http://images.slideplayer.com/38/10765527/slides/slide_54.jpg

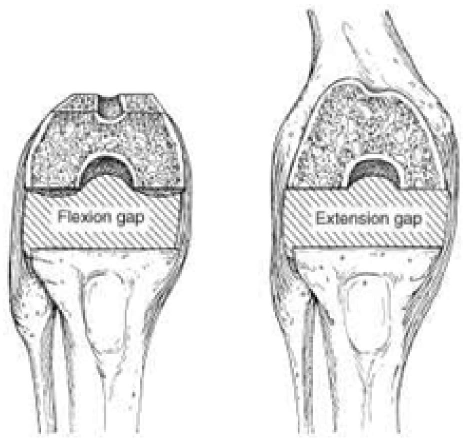


Figure 3: Gap Symmetry
Source: http://www.78stepshealth.us/knee-arthroplasty/medial-release-for-fixedvarus-deformity.html

To access the laxity of the knee before and after a TKA, surgeons will use a manual varus-valgus stress test (Figure 4). The varus-valgus stress test is a widely used tool by surgeons to qualitatively evaluate knee laxity, and is usually performed before and after a TKA. During this test, the surgeon will hold the tibia with one hand and the femur with the other and move the knee medially (towards the middle of the body) and laterally (away from the middle of the body) in both flexion and extension in order to determine if the soft tissue needs to be adjusted pre-operatively and if the knee laxity "feels" normal after the operation. There is no definition for how a knee should feel because stability is not quantified.

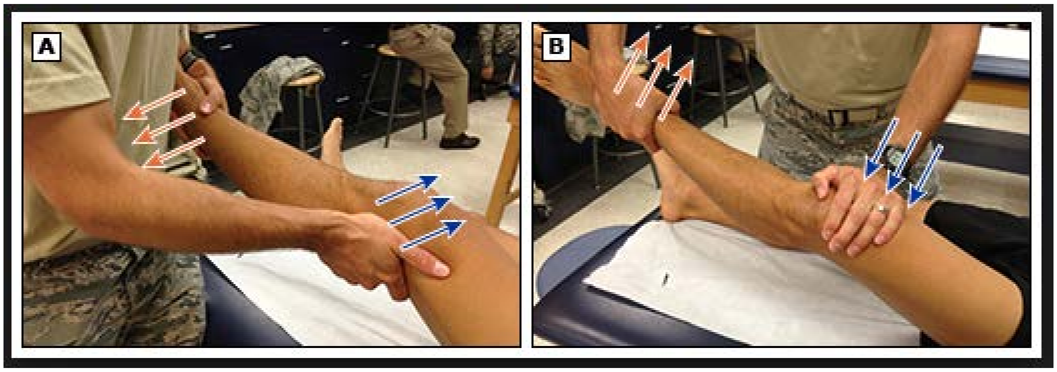


Figure 4: Varus-valgus stress test
Source: http://s0www.utdlab.com/contents/image.do?imageKey=EM%2F89745

Since the manual varus-valgus stress test is largely qualitative, this could lead to variability in TKA outcomes. This variability could negatively affect the performance of the TKA and could cause failure in the prosthetic joint, which can lead to revision surgeries. If the accuracy of the surgeon's ability to determine knee laxity is quantified, then this can determine if the surgeon's feel for knee laxity is a large contributing factor to the variability of TKAs or if the variability is more likely from a different component of the procedure.

1.1. Purpose of Thesis

The purpose of my research was to design a realistic knee model that could be used as a baseline to vary laxities in order to assess a surgeon's ability to determine knee laxity.

1.1.1. Objectives

The objectives that needed to be achieved in order to complete this research were to design and validate realistic knee models in both flexion and extension that can be altered to create varying laxities, and to have the surgeons perform the varus-valgus stress test on these models (Table 1).

Table 1: Objectives of the Thesis

Objectives	
Design Normal Knee Prototype	Extension
	Flexion
Validate Normal Knee Prototype using the Stability Rig [9]	Extension
	Flexion
Create Varying Laxity Models	
Test Surgeons and Analyze Results	

1.2. Significance of Research

By studying a surgeon's ability to determine knee laxity, it may be shown how much the surgeon contributes to variability in a TKA. If this study shows that a surgeon's ability to determine laxity of the model knees is not accurate, then more objective ways may need to be developed to measure knee stability. The results of this study could validate the current procedure for a varus-valgus stress test, or could potentially determine that improved training modules need to be developed for orthopedic surgeons that perform TKAs.

1.3. Overview of the Thesis

This thesis consists of 5 chapters. Chapter 2 includes the methodology of this research. This chapter explains prototype development and testing. Chapter 3 includes the results of the prototype and final models. Chapter 4 contains the discussion. Chapter 5 includes the final conclusions and takeaways from the thesis.

2. Methodology

2.1. Methodology Overview

The first step was to design normal, or control, knee models in flexion and extension. The models were based off of Sawbones, which was an existing product that consists of a foam core model tibia and femur (Figure 5). Different materials for knee components were explored in order to make the knee models as realistic as possible. The main focus for the models was the medial and lateral collateral ligaments (MCL and LCL), since these ligaments resist valgus and varus motions. The models were designed to be simple, meaning that the MCL and LCL on the model carried the majority of the applied load in either the varus or valgus direction (some of the load was taken by tibiofemoral contact forces). The modeled MCL and LCL had to compensate for other ligaments, tendons and soft tissues that are not modeled. This simplistic design made the analysis more straightforward, and more complex designs could use this design as a baseline.

Figure 5: Sawbones
Source: http://www.sawbones.com/Catalog/Orthopaedic%20Models/Knee/1145

The design objectives of the models were to be realistic, repeatable and reproducible and safe (Table 2). Being realistic was an important objective to ensure that the data collected from the surgeons was accurate. The surgeon would most likely not give accurate results if the motion or feel of the model did not feel natural. Repeatability of the models was also important because if the model moved a different way each time a varus-valgus stress test was performed, the data collected from the surgeons would not correctly determine if the surgeon could determine the models' laxities. Safety was also chosen as an important objective due to the involvement of the surgeons.

The models were designed to be realistic in appearance and motion. Appearance was addressed by using Sawbones, since Sawbones are a widely used tool by clinicians (Table 3). The surgeon would better be able to perform a more accurate varus-valgus stress test on Sawbones, rather than another form of "bones" that they're not familiar with (e.g., if wood was used in the final model as the tibia and femur). For realistic movement of the knee, literature was used as a guide for how the knees moved in varus and valgus (Figure 6) [17]. In Figure 6, the extension line showed a nearly linear correlation between the moment and the varus and valgus rotations. From this, the slope was estimated to be about 10 Nm/degree for both varus and valgus.

The models were also designed to be reproducible and repeatable. The tests should be repeatable so that each time the models were used, they moved the same for each surgeon. This means that at a certain applied moment, the models had the same degree of varus/valgus rotation each time the test was performed. The model had to be reproducible, so that the model could be replicated. Repeatability was analyzed by measuring the resting varus/valgus angle and the slope and trend of the line. These components should not change from test to test for a high repeatability.

Safety was an important objective because this research involved humans. Safety meant that nothing came off the model unexpectedly and nothing was sticking out from the surgical wrap that could hurt someone. This was addressed by using the surgical tape so that the surgeon would not be in contact with the mechanical portion of the knee. The surgeon only came in contact with the Sawbones.

Table 2: Objectives of the Designed Knee Models

<table>
<tr><th colspan="2">Objective</th><th>Metric</th></tr>
<tr><td colspan="2">Safe</td><td>Number of safety hazards</td></tr>
<tr><td colspan="2">Repeatable and Reproducible</td><td>Success percentage</td></tr>
<tr><td rowspan="2">Biofidelic</td><td>Appearance</td><td>Based from Sawbones</td></tr>
<tr><td>Motion</td><td>Extension: linear trend Flexion: cubic trend</td></tr>
</table>

Table 3: Sawbones Specs

Component	Value
Femur canal diameter	16 mm
Femur overall length	47 cm
Tibia canal diameter	12.5 mm
Tibia overall length	42 cm

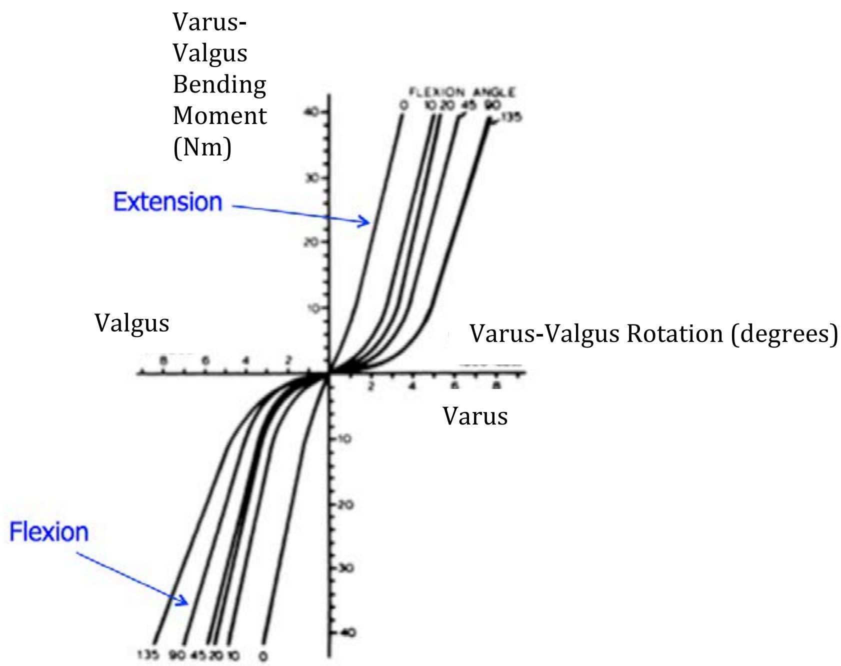


Figure 6: Moments depending on Varus and Valgus Position
Source: Markolf, K. L., et al. The Journal of Bone and Joint Surgery.

The main function of the model was to be able to move in varus and valgus in both flexion and extension (Table 4). The requirements for these functions were based off literature [17] and data collected by a previous PhD student in the Neuromuscular Biomechanics Lab [18].

Table 4: Functions for the Models

Functions	Requirements [18] (from Dr. Joe Ewing)	Requirements [17] (from Markholf et al.)
Move in Varus (Extension)	< 2.5 degrees @ 10 Nm from resting position	1 degree @ 10 Nm from resting position
Move in Valgus (Extension)	< 3 degrees @ 10 Nm from resting position	1 degree @ 10 Nm from resting position
Move in Varus (Flexion)		5 degrees @ 10 Nm from resting position
Move in Valgus (Flexion)		4 degrees @ 10 Nm from resting position

I validated the knee models using a stability rig developed in the Neuromuscular Biomechanics Laboratory at The Ohio State University (Figures 7 and 8) [9]. The stability rig used computer navigation and a load cell to record force applied to the limb and motion at the knee (Figure 7). Markers were placed on the femur and tibia to form anatomic coordinate systems and on the boot and the varus-valgus slide cart to establish a reference coordinate system [9]. The loads were applied by pushing and pulling on a load cell on a minimal friction track that was oriented perpendicular to the leg [9]. The moments were created from the reaction forces between the boot and the slide cart. The lever arm used in the moment calculation was the vector from the origin of the tibial anatomic coordinate system to the origin of the slide's coordinate system [9]. After collecting the applied moment and the corresponding varus and valgus angles, I graphed the data in MATLAB and compared the data to literature [17] (Figure 6) and previous data collected in the Neuromuscular Biomechanics Laboratory [18] to verify that the knees had the same laxities as average knees. There were multiple trials with each knee and multiple testers to ensure that the knee models were validated correctly.

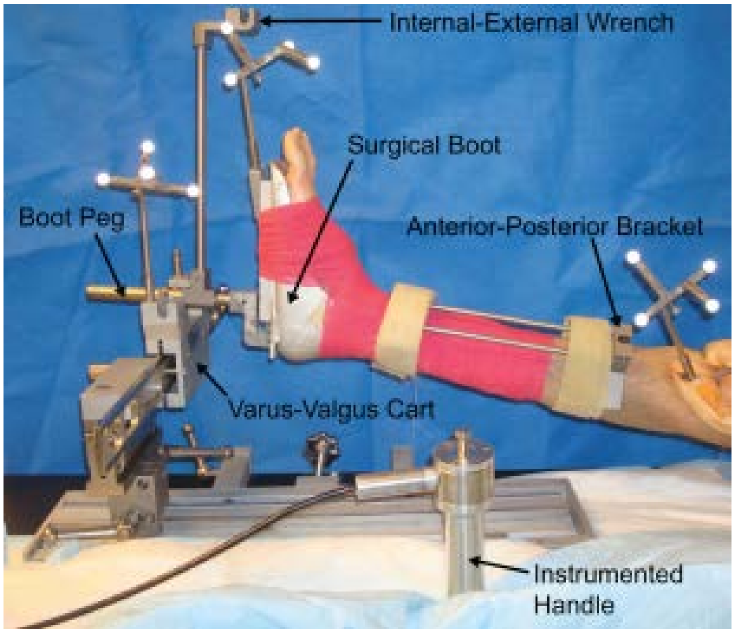


Figure 7: Stability rig
Source: Siston, R. A., et al. Journal of Biomechanical Engineering

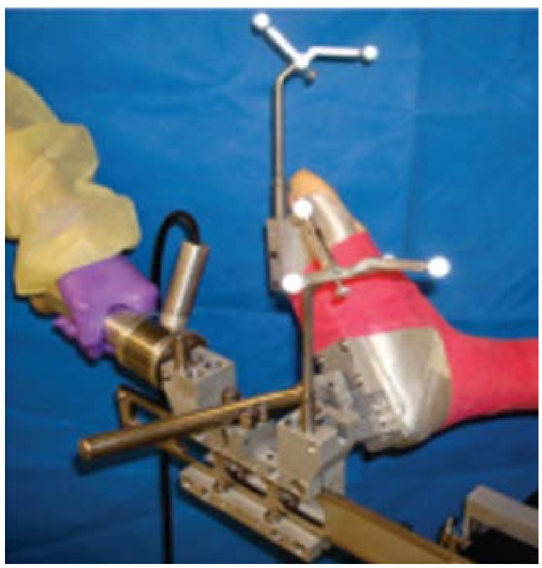


Figure 8: Performing varus-valgus stress test with Stability rig

2.2. Analysis of Materials

Different materials were analyzed in order to determine which ones were feasible and to determine initial estimates, such as length or thickness of the materials, for experimentation. First, general decisions about the collateral ligament materials will be discussed. Then, there will be further explanation of leaf springs, the flexion hole, tension springs and elastic material.

2.2.1. Collateral Ligament Approaches (Early Decisions)

I developed a design matrix in order to explore material options for the collateral ligaments that best replicated the motion of a knee, while maintaining a reasonable size (Table 5). Ability to vary stiffness and repeatability were weighted the highest because these objectives directly applied to the purpose of this research. In other words, if the ligament material was not able to be varied in stiffness, then the surgeon's ability to determine knee laxity would not be able to be tested. For repeatability, if the models were not consistent, then data collected from the surgeons would not be useful. The materials had to be reasonably small in order to make sure that the knee did not look abnormal, so size had an indirect effect on the surgeons giving accurate results when they performed the varus-valgus stress test on the models. Since all of the mechanical components of the model knees were to be covered, each material received the same score in the "safety" category, so safety was not a factor in this design decision.

The materials were ranked using these objectives. Leaf springs were rated higher in terms of varying the stiffness because leaf springs had to the ability to add or subtract leaves to increase or decrease the stiffness of the knee. Tension springs could be placed in parallel with one another, but increasing the number of tension springs would drastically change the size of the knee compared to leaf springs, which is also why leaf springs rated higher than tensions springs in the "small" category. Stiffness could also be varied by choosing springs with different stiffnesses, but stiff springs may be limited to only certain stiffnesses. Elastic material were rated the highest in the "small" category because elastic materials had the ability to compress when they were placed in parallel with one another. However, elastic material ranked the lowest overall because there was not an accurate way to determine the stiffness of the elastic material since it was the most likely to stretch and become plastically deformed unless the material had a high yield strength.

Table 5: Design Matrix for Collateral Ligaments

	Weight	1	2	0.5	1.5	2	
		Safe	Able to Vary Stiffness	Easy to Implicate	Small	Consistent	Total
Materials	Leaf Springs	2	2	1	1.5	2	**12.75**
	Tension Springs	2	1.5	1	1	2	11
	Elastic Material	2	0.5	1.5	2	-1	4.75
	Ranking: 2 = good 0 = neutral -2 = will negatively affect device						

Overall, the leaf springs received the highest score, so leaf springs were used as the first material to analyze and test; however, all materials in this design matrix were used in the experiments in order to ensure that the optimal material was chosen for the final design.

2.2.2. Leaf Spring Design Calculations

The leaf springs were modeled as cantilever beams that were fixed at one end with a moment applied at the other. In this model, the beams represented the leaf springs as the collateral ligaments. One end was fixed and the other was free because the varus and valgus angles were measured from one bone with respect to the other bone, so the problem was simplified by fixing the femur (Figure 9). Equation 1 was used to relate the varus and valgus angles to the applied moment using the stiffness [19].

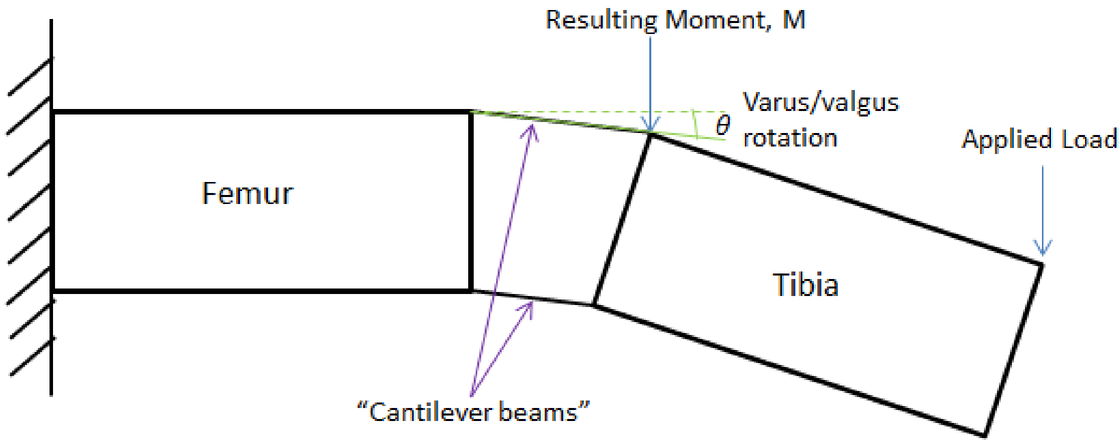


Figure 9: Cantilever Beam Model shown as femur and tibia

$$\theta_{max} = \frac{M}{k_{eq}} \qquad Equation\ 1$$

Equations 2 and 3 were used to calculate the stiffness needed for the leaf spring [20].

$$k = \frac{E * n * b * t^3}{6 * L^3} \qquad Equation\ 2$$

$$k_{eq} = k_1 + k_2 \qquad Equation\ 3$$

$$E = Young's\ Modulus$$
$$n = number\ of\ leaves$$
$$b = width\ of\ leaves$$
$$t = thickness\ of\ leaves$$
$$L = span$$
$$k = stiffness$$

Using these equations, I calculated the variables for the leaf springs. To replicate literature, the constraint that I used was a slope of 10 Nm/degree [17]. Aluminum 6061, with a Young's Modulus of 68.9 GPa, was chosen as the material because it had the ability to be easily machined. The thickness was determined from available thicknesses of sheet metal, so a thickness of .0004 m was chosen. The width of the of the leaf spring was chosen in a similar manner, so the width was chosen to be .0508 m. Using these parameters, the number of leaves and length of each leaf spring was adjusted until a slope of 10 Nm/degree was obtained. The number of leaves was calculated to be 1 and the thickness of each ligament was about .05 m (Figure 10). Comparing Figure 10 to Figure 6, Figure 10 showed a slope of about 10 Nm/degree, which is consistent with literature [17].

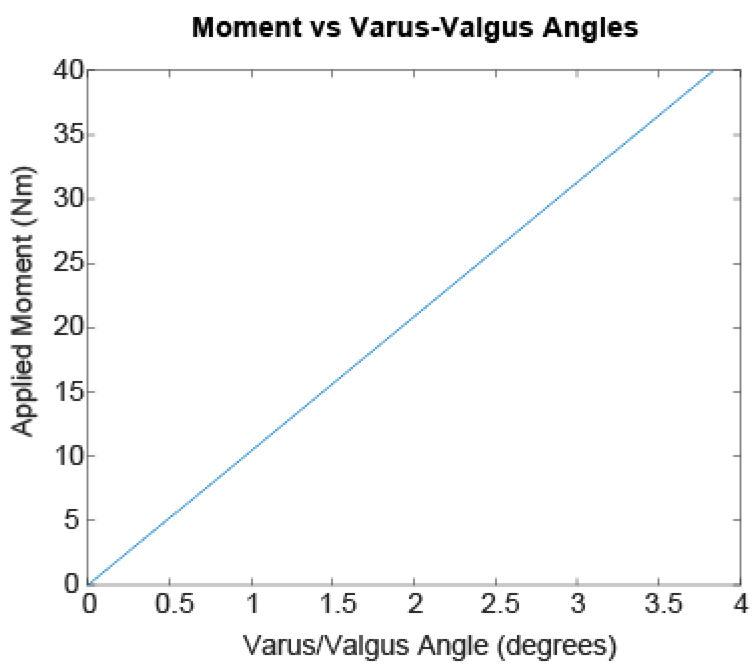


Figure 10: Angle vs Moment Plot for the Designed Leaf Springs

2.2.3. Flexion Hole Analysis

Based on the trend from literature during flexion, the knee was lax until approximately 4-5 degrees of varus or valgus rotation before reaching a terminal stiffness, or linear trend, which was approximately the same stiffness as the extension line [17]. This is shown by the curve on the flexion line (Figure 6). One proposed way of achieving this laxity was by making a slightly larger hole for a shaft (the shaft was used to mount the springs) (Figure 12). This caused the shaft to not be in contact with the Sawbones until a certain degree of varus or valgus rotation was achieved. The analysis is shown below (Figure 11 and Figure 12). A simplifying assumption was made that the movement of the point on the end of the shaft was approximately the size of the flexion hole. Figure 13 and 14 show how the shaft would move (as the tibia was being rotated in varus or valgus) in the larger hole and the corresponding curve from the Markholf study [17].

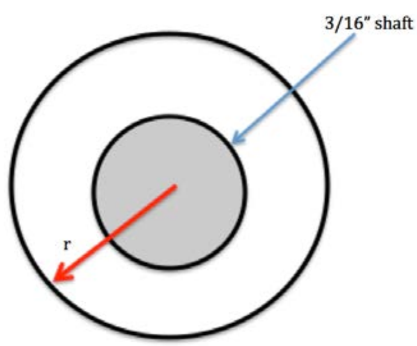
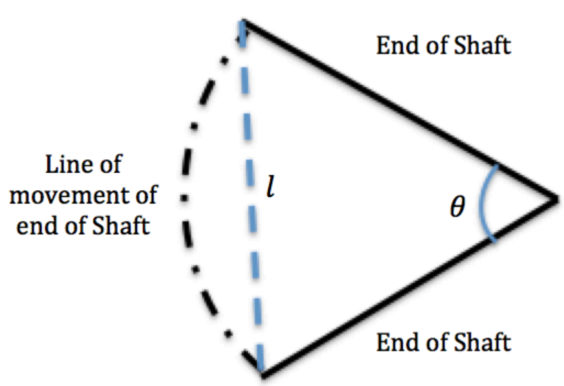


Figure 11: Side View Schematic of Flexion Hole on the femur



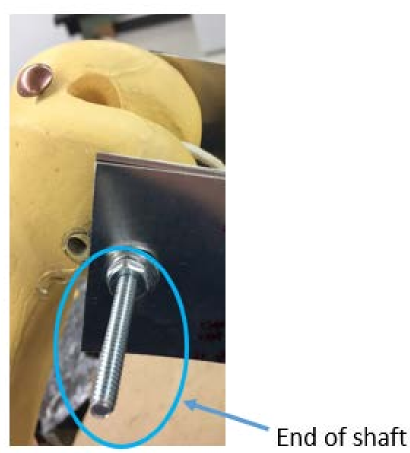


Figure 12: Front View Schematic of Flexion Hole on the femur

$$r = radius\ of\ the\ hole$$
$$l = approximate\ amount\ the\ end\ of\ the\ shaft\ would\ move$$
$$\theta = angle\ that\ the\ shaft\ would\ shift$$

$$Assumptions:$$
$$end\ of\ shaft = 1.375\ in$$
$$\theta \approx 5°$$
$$Calculations:$$
$$\sin(5°) = \frac{l}{end\ of\ shaft} = \frac{l}{1.375\ in}$$
$$l = 0.1198\ in$$
$$2r = shaft\ size + l = 0.1875\ in + 0.1198\ in = 0.3073\ in\ \approx \frac{5}{16} in$$

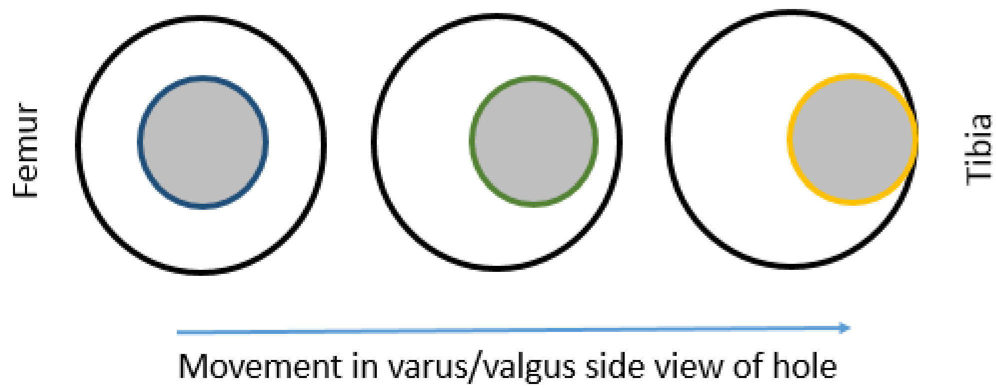


Figure 13: Side View schematic of moving shaft (corresponds to Figure 14)

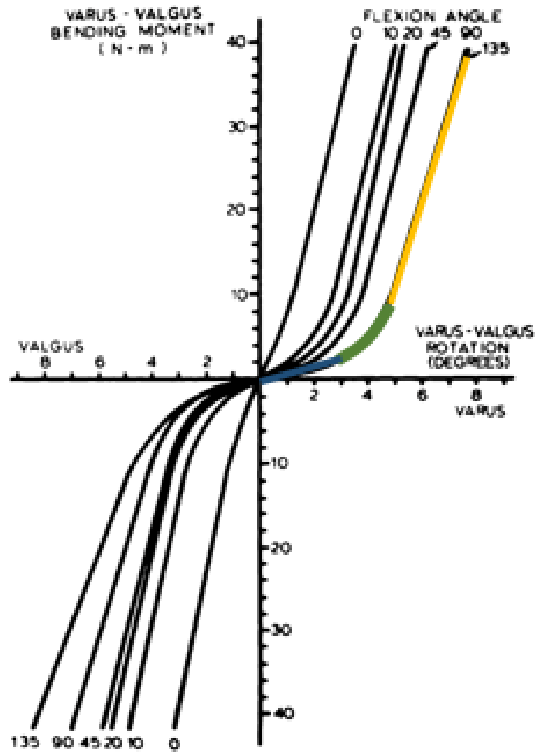


Figure 14: Corresponding graph to moving shaft
Source: Markolf, K. L., et al. The Journal of Bone and Joint Surgery.

2.2.4. Tension Spring Design Calculations

Tensions springs were also analyzed because tension springs only held load in tension, and theoretically would not hold the load in compression, much like the MCL and LCL. So when a moment was applied, only one tension spring was stretched while the other tension spring was lax.

To get a design that follows a study from literature, at an applied moment of 10 Nm, the tibia moved approximately 1-1.5 degrees in varus or valgus [17]. A schematic of the system for the frontal plane of a left leg is shown below (Figure 15). In the schematic on the left, the tensions springs was at a preloaded (initial) length and the springs on the medial and lateral side was the same length. On the schematic to the right, the tibia was rotated slightly relative to the femur in valgus. The lateral side spring was lax, so only the medial side spring was in tension. The rotation of the tibia results in a valgus angle, with a corresponding distance, x. This distance, x, was assumed to be equal to the distance that the spring would stretch, l_2. The spring stiffness was calculated to be around 16,000 N/m.

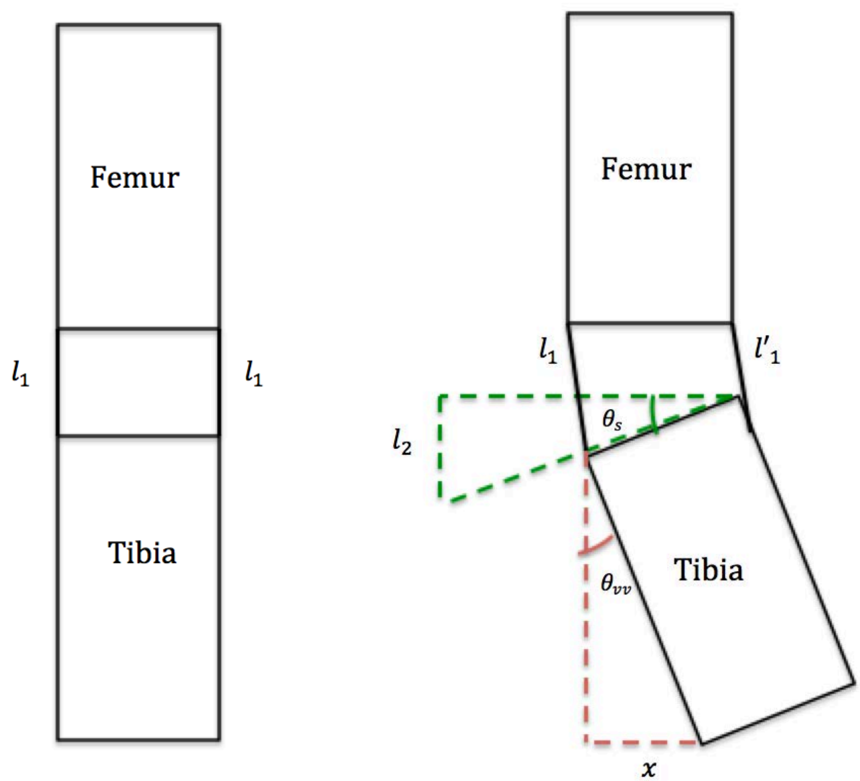


Figure 15: Tension Spring Schematic

$$l_1 = initial\ length\ of\ tension\ of\ spring$$
$$l'_1 = slack\ length\ of\ tension\ spring$$
$$l_2 = approximate\ stretched\ length$$
$$\theta_s = angle\ created\ by\ stretching\ the\ spring$$
$$\theta_{vv} = varus\ or\ valgus\ angle$$

$$Assumptions:$$
$$l_1 = l'_1$$
$$\theta_s = \theta_{vv} \simeq 1.5°$$
$$l_{tibia} = length\ of\ tibia = .35m$$

$$w_{tibia} = width\ of\ tibia = .07m$$
$$M = 10Nm$$
$$Calculations:$$
$$sin\theta_s = \frac{l_2}{w_{tibia}} \rightarrow l_2 = (.07m)(sin1.5°) = 0.00183m$$
$$F = \frac{M}{l_{tibia}} = \frac{10\ Nm}{.35m} = 28.571N$$
$$k = \frac{F}{l_2} = \frac{28.571N}{0.00183m} = 15612.568\ \frac{N}{m}$$

2.2.5 Elastic Material Analysis

I decided that the best way to determine if the elastic material would result in a linear trend was through experiment. Some elastic workout bands were arbitrarily chosen for testing. These bands were layered on each other in order to increase stiffness.

2.3. Prototyping

First, the initial (wood) prototyping is be explained. Next Sawbones prototyping with leaf springs for extension builds off the initial prototyping. Sawbones prototyping with leaf springs for flexion is described after the extension section. Lastly, the spring and combination (hybrids of leaf springs, tension springs, and elastic material) prototypes are be explained.

2.3.1. Wood Prototyping

First, a SolidWorks model was created to determine what the leaf spring system would look like (Figure 16).

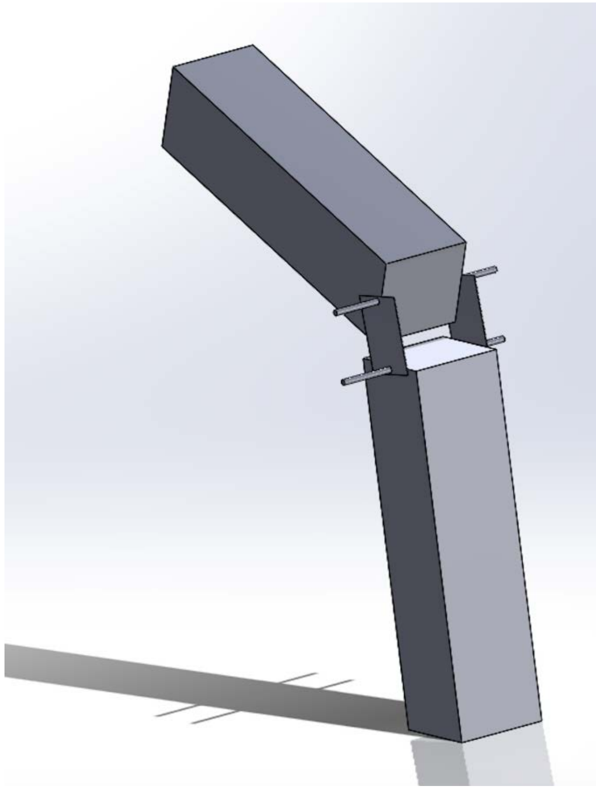


Figure 16: SolidWorks Model Knee

In order to determine whether the leaf springs produced the correct trend, I built a prototype made from wood (Figure 17). This model showed nearly linear behavior; however, the model was not stiff enough. The initial models resulted in a slope of 1 Nm/degree, which was significantly less than the desired slope of 10 Nm/degree. The model also displayed too much translation and rotation in order to get good results. Some of the applied force at the ankle may have been reflected in translational and rotational motion rather than a varus or valgus motion. The next model had an ACL and a PCL to help prevent the anterior and posterior movement, but this addition did not help with the translation (Figure 18). The wood was changed to a rectangular cross section in order to have a flat face for the leaf springs. The flat face helped increase the contact area from the leaf springs to the wood, so the leaf springs would be better fixed to the femur and the tibia.

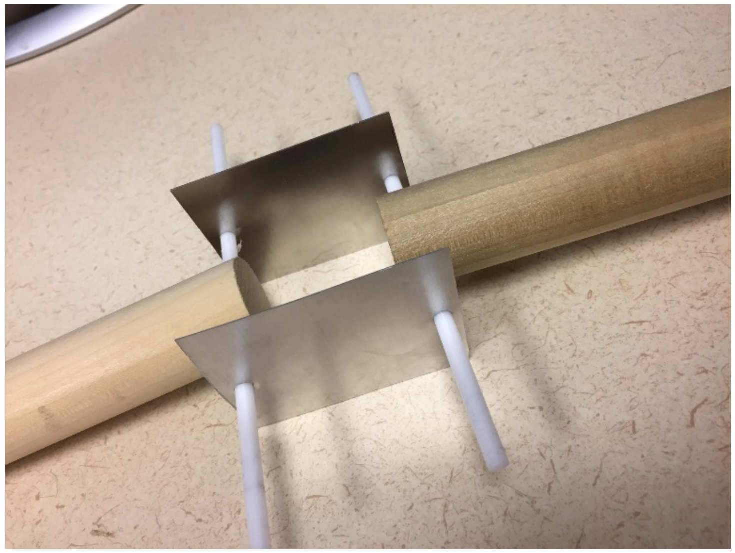


Figure 17: Prototype 1

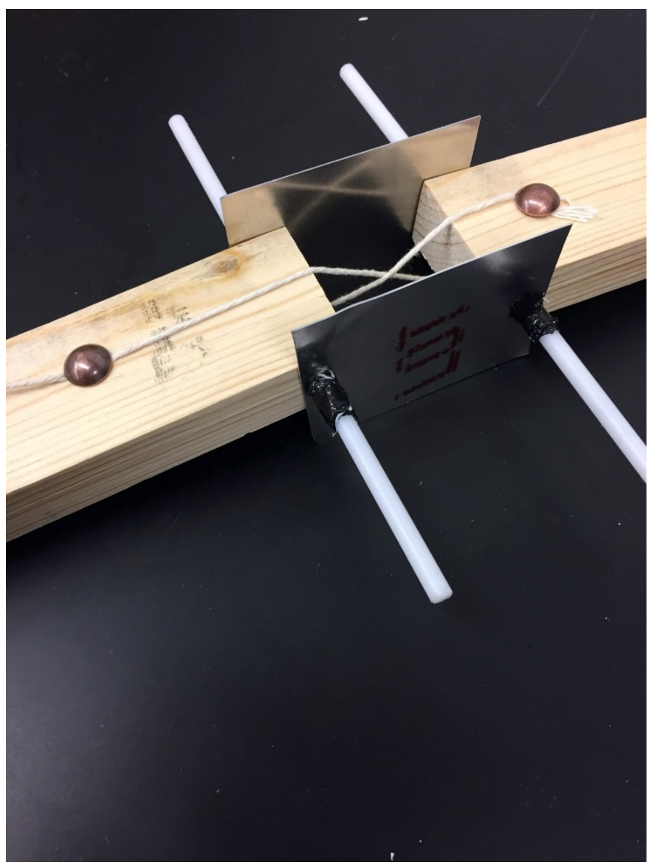


Figure 18: Prototype 2

Once the leaf springs proved to have a nearly linear trend, additional leaf springs were added in order to make the knee feel stiffer (Figures 19 and 20). This process of adding leaf springs showed that a variety of laxities could be achieved by adding and subtracting leaf springs.

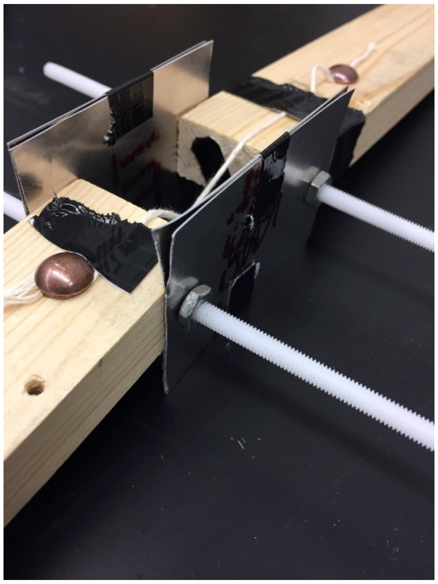


Figure 19: Additional Leaf Springs

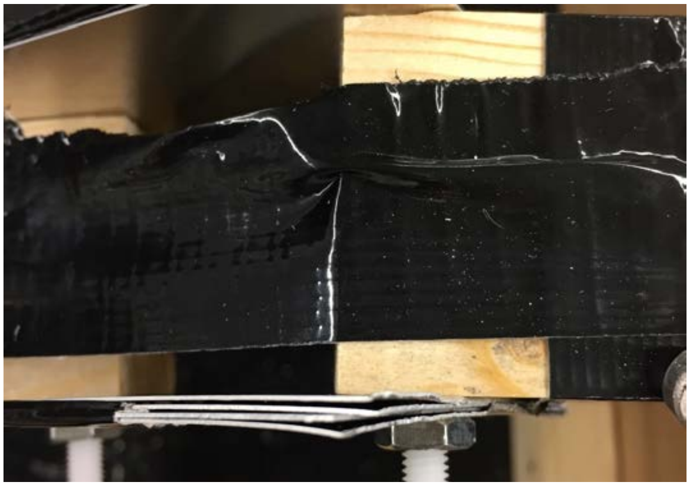


Figure 20: Additional Leaf Springs

2.3.2. Sawbones Prototyping for Extension

The wood was replaced with Sawbones to get better anatomical references for the stability rig and to test Sawbones that were similar to the Sawbones that would be used in the final model. This would help get better measurements for the applied moment and the varus and valgus angle. The first Sawbones prototype showed the desired linear behavior, but slope of the moment vs varus valgus angle graph was still too small (Figure 21). The Sawbones used was not a full-length leg, so it was also hard to test this model. The next step was to build a full-length model (Figure 22). A third shaft was added in order to prevent rotational motion around the anatomical axis. This model also proved to be too lax. To decrease the laxity, the plastic shafts were replaced with metal shafts and more leaf springs were added.

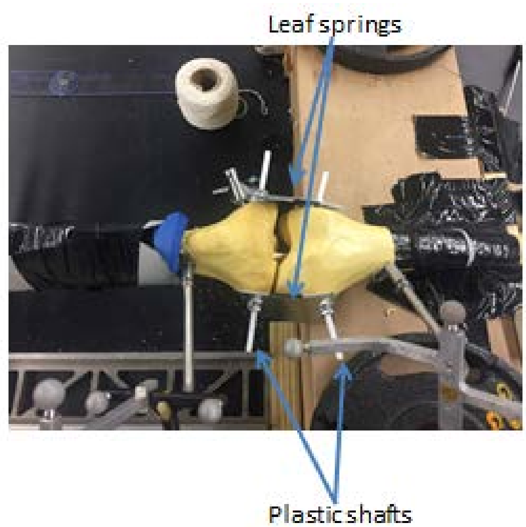


Figure 21: Sawbones Prototype

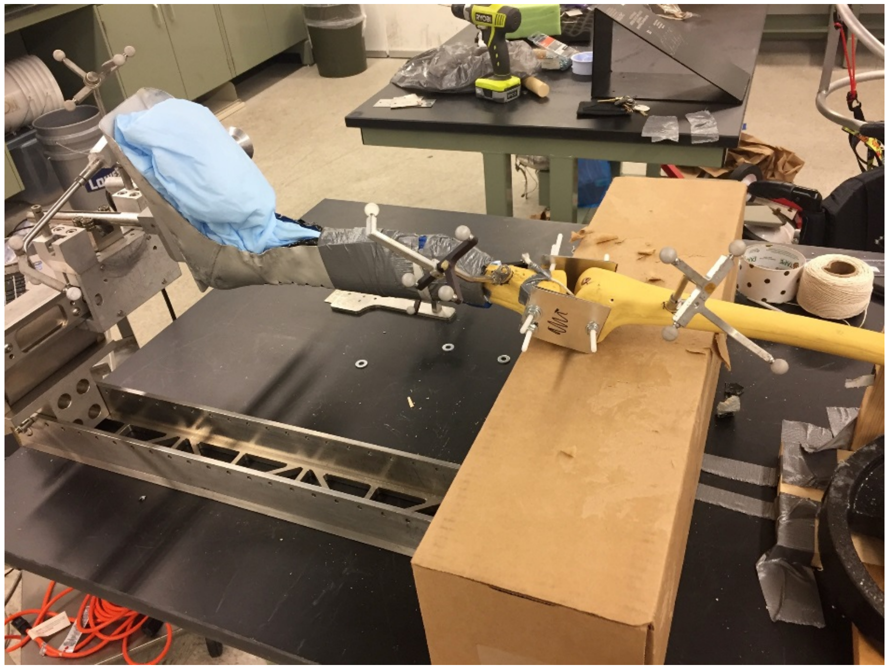


Figure 22: Full Length Sawbones Model

In the final extension prototype, all plastic shafts were replaced with metal shafts and 7 leaf springs were placed on both the medial and lateral sides of the knee (Figure 23).

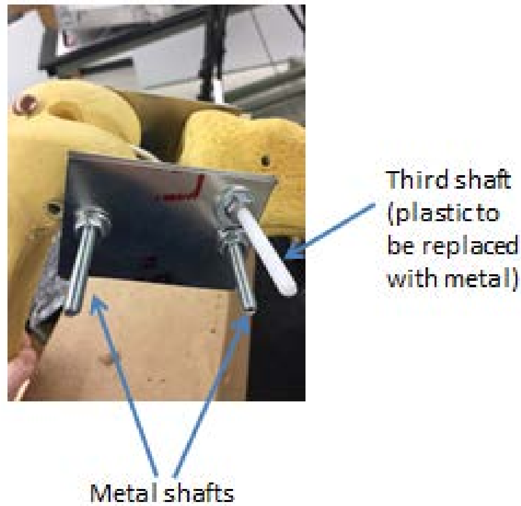


Figure 23: Sawbones Prototype with Metal Shafts

2.3.3. Sawbones Prototyping for Flexion

Using the analysis from section 2.2.3 of this report, a 5/16 in diameter hole was drilled into the femur of the extension prototype. In Figure 23, the hole is shown as the larger hole to the left of shaft that is through the femur.

2.3.4. Tension Spring and Combination Prototype Models

Multiple tension prototypes were tested using different spring stiffnesses, different amounts of springs in parallel, and different orientations of the tension springs (Figure 25-29). Figure 25 shows two commercially available springs on both the medial and lateral side. This model gave a linear trend, but the knee was rotated about 15 degrees in valgus at 6 Nm, which is too lax. The spring on the side that was not being stretched did not buckle, so it formed a column and an increasing moment resulted in a constant varus and valgus angle. It was difficult to find a spring with the stiffness calculated in section 2.2.4. because the spring needed to be long enough so that there was a gap between the tibia and femur to allow the tibia to rotate (varus/valgus), while still having a diameter that allowed for the knee to have a realistic size. The chosen springs also needed to be able to buckle when they were not in tension in order to prevent having a column on one side of the knee. The springs in this prototype best fit the design criteria by showing proof of concept, but did not produce the desired result.

To increase the stiffness, a leaf spring was added in parallel. However, during testing, the leaf spring deformed when the model was rotated to a certain angle (Figure 26). To solve this issue, more leaf springs were added in parallel on both the medial and lateral side, but after adding a few more leaf springs, the effect of the tension spring was no longer apparent (the tension spring was not stretched).

Cartilage was added to the model in order to reduce the load on the springs. As shown in Figure 27, cartilage (green foam) was added to some of the models to see if it would alter the result (e.g., reduce the amount of stiffness required by the ligaments), but there was not much of an effect.

Figure 23 shows the addition of an elastic material (Figure 24), which ideally would be slack on one side while the other side was in tension like the tension springs. The elastic material was not stiff enough and the elastic component could not be tested without using either a leaf spring or tension spring in parallel.

Figure 24: Elastic Material
Source: https://www.starwoodsports.com/products/resistance-bands?utm_medium=cpc&utm_source=googlepla&variant=10454995203&gclid=CKyR3_KZn9MCFUOewAodAnMDcA

Some of the figures (Figures 27 and 29) show different orientations of the tension spring to determine if a different effect from Figure 25 occurred (e.g., show a different trend or different stiffness), but for the most part, all of the tension spring graphs were the mostly linear, but not stiff enough. An example result is shown in Figure 30.

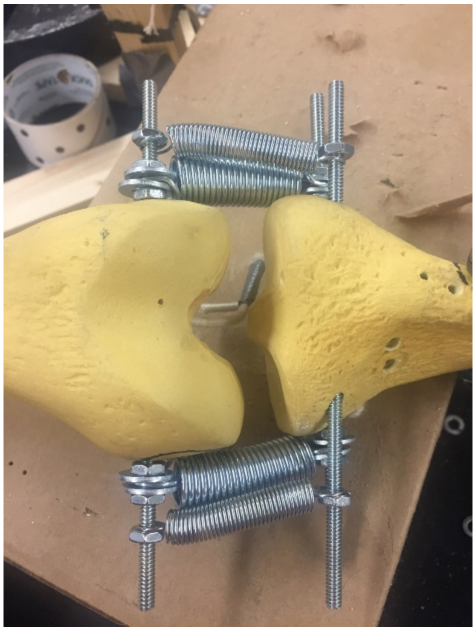


Figure 25: Tension Springs in Parallel

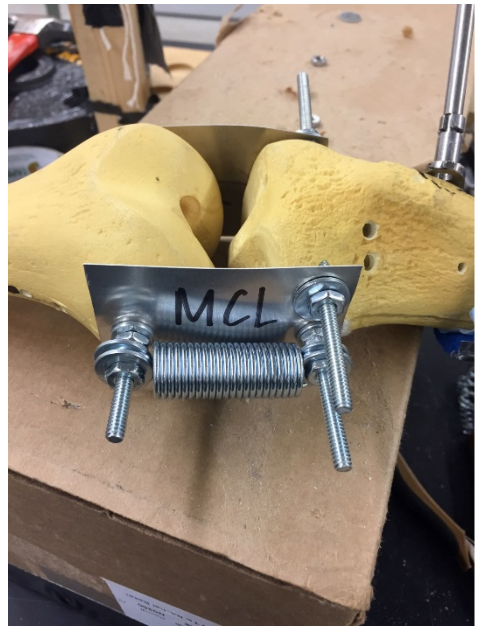


Figure 26: Tension Spring and Leaf Spring in Parallel

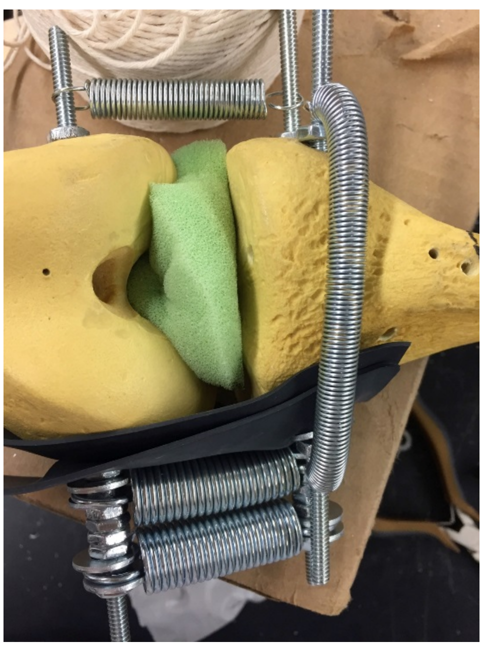


Figure 27: Tensions Springs in Different Orientations with Foam Cartilage

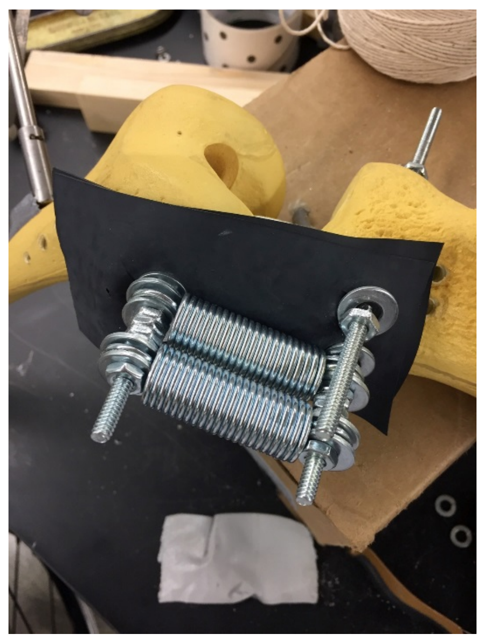


Figure 28: Tension Springs in Parallel with Elastic Material

Figure 29: Tension Springs in Parallel with Leaf Springs and Elastic Material

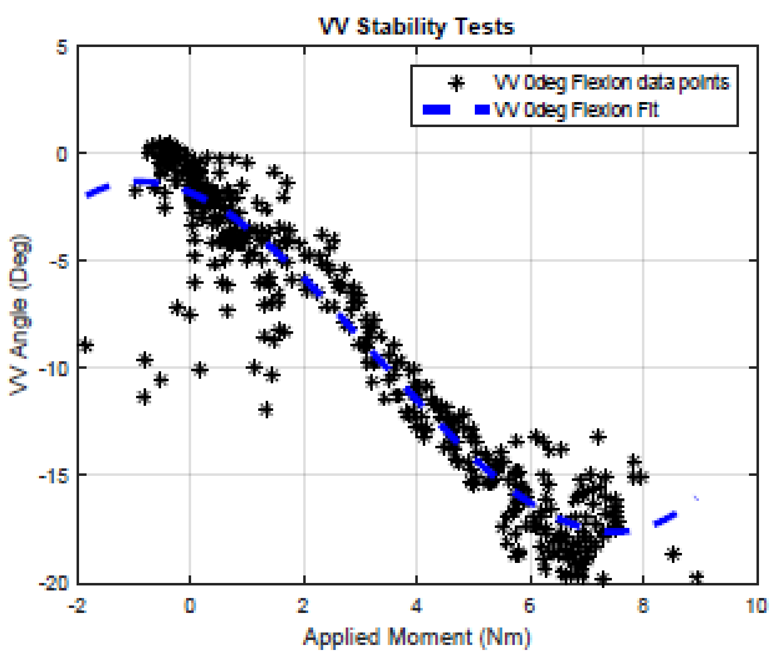


Figure 30: Example Tension Spring results

3. Results

3.1. Initial Prototype Testing

The results of the prototypes in sections 2.3.2. and 2.3.3. are explained in the following sections.

3.1.1. Extension Prototype

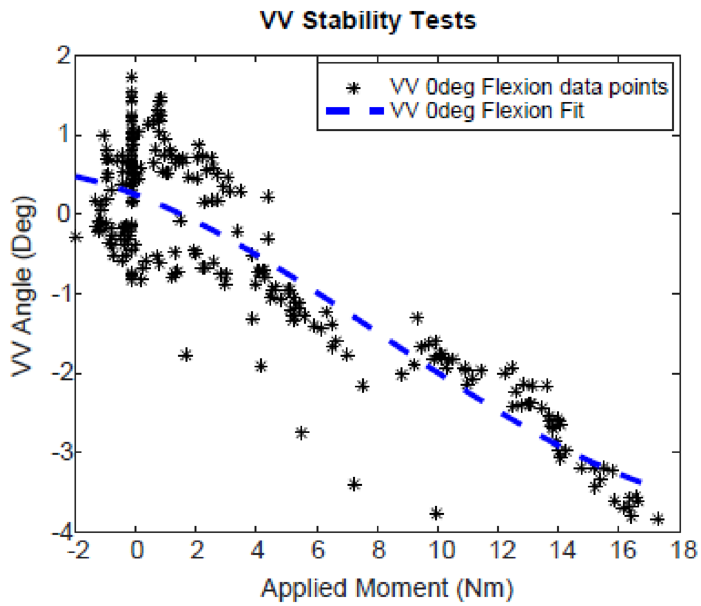


Figure 31: Moment vs Angle for Final Extension Prototype

This graph above showed that at 10 Nm, the knee rotated 2.25 degrees (Figure 31). While this was slightly larger than what was shown in Figure 5, the data matched data collected from cadavers from a previous Neuromuscular Biomechanics Laboratory graduate student. This previously collected data showed that, on average for extension, the knee rotated 2.48 degrees in varus and 2.84 degrees in valgus at 10 Nm [18].

3.1.2. Flexion Prototype

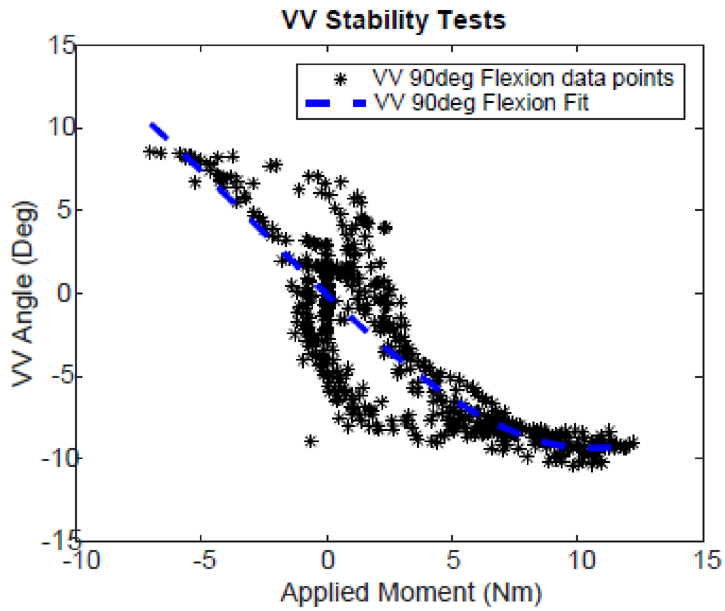


Figure 32: Moment vs Angle for Sawbones Flexion Model

In Figure 32, the linear line (terminal stiffness) began around 7 degrees valgus. In the Markholf study, the linear line started at about 5-6 degrees [17]. The results showed a slightly more lax knee than the Markholf study (Figure 6), but the results followed the correct general trend [17]. To decrease this laxity, the hole needed to be drilled slightly smaller in the final model.

3.2. Final Extension Model

The final extension model was very similar to the prototype; however, 8 leaf springs were used instead of 7 leaf springs (Figure 33). Slight adjustments were made to the model due to the different size and geometry of the final model Sawbones.

Figure 33: Final Sawbones Extension Model

3.2.1. Results of Final Extension Model

The results from the final extension model showed a somewhat linear trend with variation around 0 Nm (Figure 34). In varus, by extrapolating the trend line, the model rotated about 2.75 degrees. In valgus, the model rotated 1.25 degrees at 10Nm.

In another trial, another researcher from the Neuromuscular Biomechanics Lab performed the varus-valgus stress test on the model knee (Figure 35). There were only two data points in varus, so the varus data from this graph was most likely not an accurate representation. In valgus, the knee rotated about 2.5 degrees at 10 Nm.

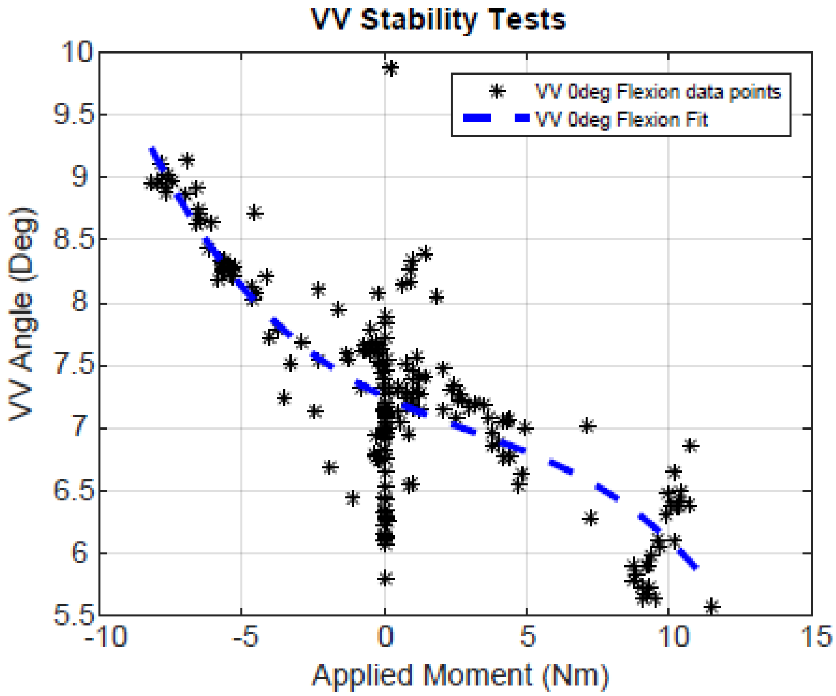


Figure 34: Results from Final Extension Model

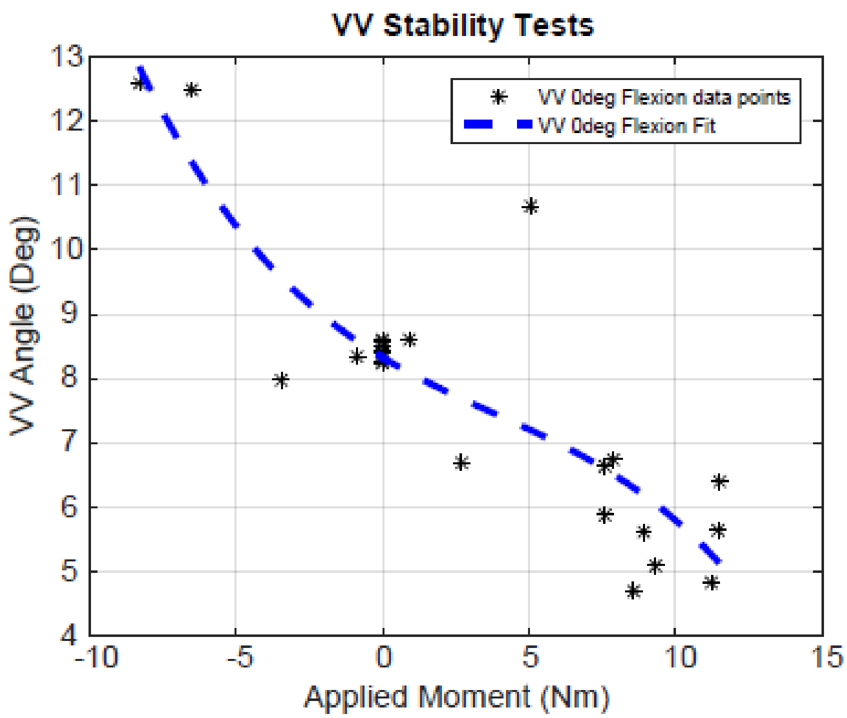


Figure 35: Results from Final Extension Model from different tester

3.3. Final Flexion Model

The flexion model was slightly different than the prototype model (Figures 36 and 37). The ACL and PCL were retained in the model in order to try to reduce the amount of variability in the model at the initial varus or valgus angle (0 Nm).

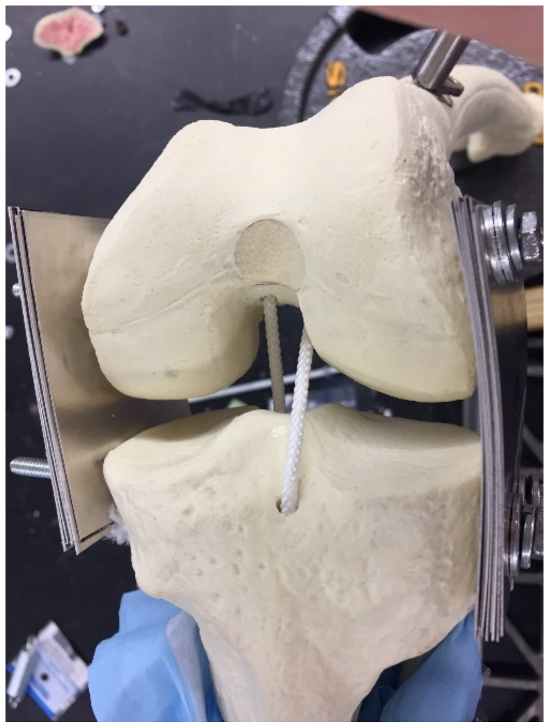


Figure 36: Final Flexion Model top view

Figure 37: Final Flexion Model side view

3.3.1. Results of Final Flexion Model

The final flexion model had a slightly curved trend before reaching terminal stiffness at about 8-9 Nm (Figure 38). If the trend were to continue, the flexion model rotated about 4 degrees in valgus and 5-6 degrees in varus. However, these varus and valgus rotations were only estimated since the maximum applied moment in either direction was about 8 Nm.

Some of the trials showed the opposite trend from what was desired (Figure 39). The model knee was very stiff at first and then became lax, rather than being lax first and then reaching a terminal stiffness.

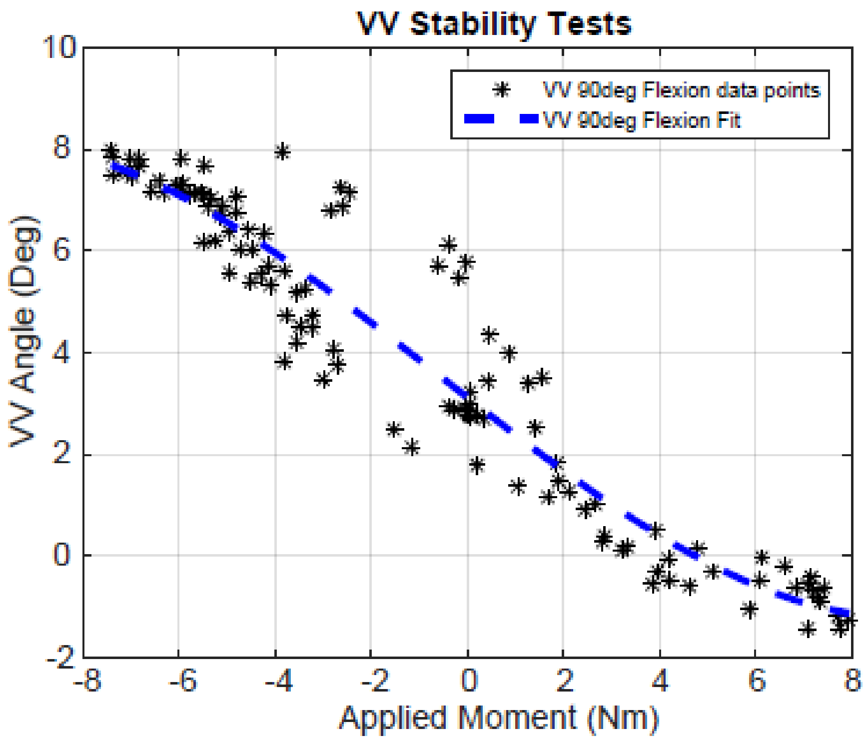


Figure 38: Final Flexion Model Results

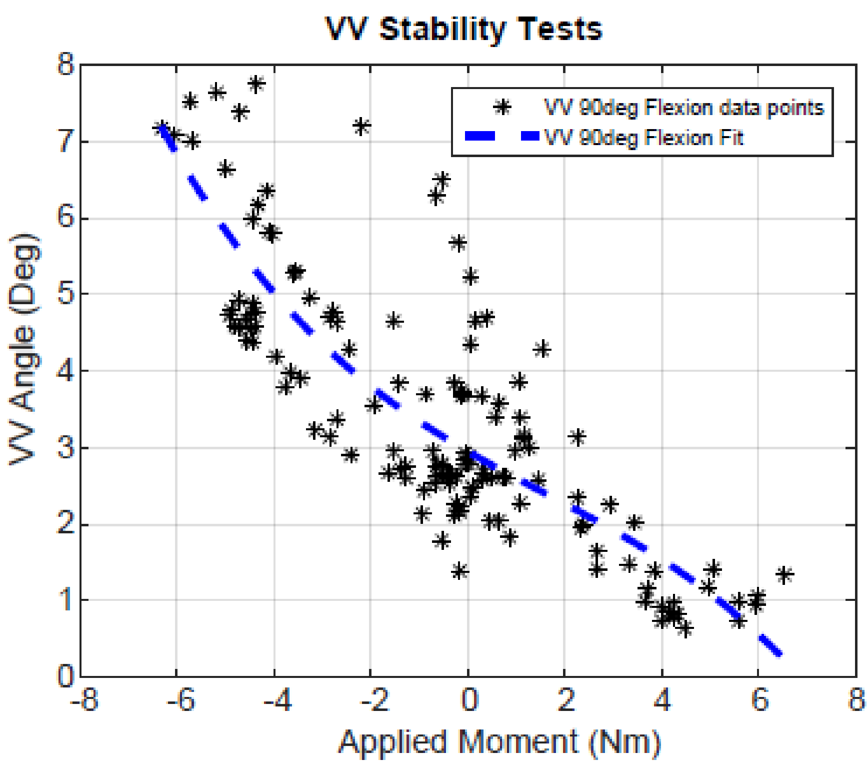


Figure 39: Final Flexion Model Results – Consistency issues

4. Discussion

The purpose of this research was to design a realistic knee model to test a surgeon's ability to determine knee laxity. Designing and validating the model prototype was completed for the knee model in extension (check mark), and the flexion model was almost complete (question mark) (Table 6). The flexion model needed to be further developed in order to have less variability during the varus-valgus stress test. Creating the laxity models and testing surgeons is future work.

Table 6: Objectives Status

Objectives		Status
Design Normal Knee Prototype	Extension	✓
	Flexion	✓
Validate Normal Knee Prototype using the Stability Rig	Extension	✓
	Flexion	?
Create Varying Laxity Models		Future Work
Test Surgeons and Analyze Results		Future Work

For extension the results of the final model compared well with data collected by Dr. Joe Ewing [18]. In the first trial (Figure 34), The final results differed by 0.25 degrees (lax) in varus and 1.25 degrees (stiff) in valgus [18]. In the trial performed by another tester (Figure 30), the results differed by 0.5 degrees (stiff) in valgus [18].

The extension results also compared well to the Markholf study [17]. The first trial differed by 1.75 degrees (lax) in varus and 0.25 (lax) in valgus [17]. The trial performed by another tester differed by 1.5 degrees (lax) in valgus [17].

The final flexion model compared well to the Markholf study [17]. The model differed by almost 0-1 degrees in valgus and 0-1 degrees in varus [17]. Even though this was fairly consistent with literature, there were consistency problems with this model. The same trend was not achieved each time that a varus-valgus stress test was performed on the model. This may have been due to different "starting points" of the shaft. In other words, the shaft could already be up against one of the sides of the hole at the start of a varus or valgus excursion, which would cause the model to seem stiff, like the extension model.

One way that may prevent the inconsistent trend would be to put a compressible material around the shaft in the large hole for flexion. This may help the shaft return to the middle of the hole so that the shaft has the same starting place for each excursion of varus or valgus.

Limitations of the model included repeatability, the material of the Sawbones and leaf springs, and the lack of data above 10 Nm. The model was not repeatable from test to test as I originally thought. Some tests had more variability than others and some tests did not show the same trends. This inconsistency could be caused by performing the varus-valgus stress test slightly different for each test (e.g., the model could be rotated around its anatomical axis in one test more than another). For flexion, the issue could have been the bigger hole for the shaft. I could not be sure where the shaft was sitting in the hole, so it is possible that for some tests, the shaft was already against the wall of the bottom of the hole instead of resting at the top of the hole. For some models, different testers yielded different results. This could be caused by the testers holding the model differently or preforming the test differently from one another. It may also be difficult to vary the laxity of the models medially and laterally since the leaf springs acted on both the medial and lateral side in both varus and valgus. Another issue that arose during testing was the material of the Sawbones. During one of the tests, the femur snapped off where the shaft went through the bone (Figure 40). This could have been due to too high of an applied moment (e.g., impulse moment) or fatigue of the model. Lastly, there was a lack of data above 10 Nm. Some surgeons may be able to obtain a moment larger than 10 Nm, so I was not confident that the trend continued past 10 Nm since most of the trials were less than 10 Nm.

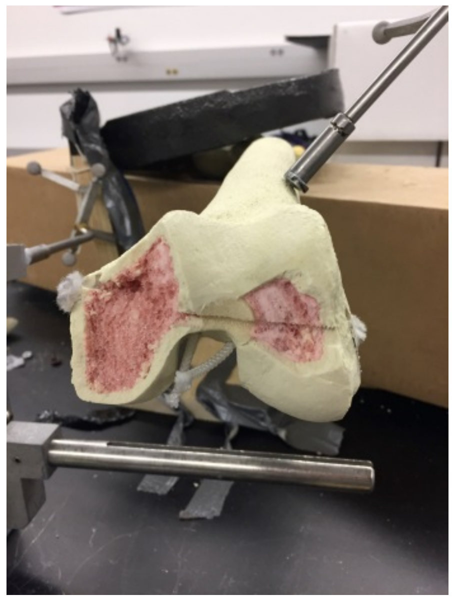


Figure 40: Broken Sawbones

The appearance of the model could be improved to look more "realistic", as well as feel more like a normal knee. Sawbones proved to not be successful when it came to weight and strength of the femur and the tibia. Since the Sawbones broke during one of the tests, using a material for the bones that is heavier and it able to withstand the forces applied at the site of the shafts would improve the model. This would also help make the knee feel more realistic for when the surgeon performs the varus-valgus stress test. Other types of coverings, besides surgical tape, should be considered. There are "knee" coverings that are sold through Sawbones that look more like a realistic knee.

An improvement to the model could be made by putting a spacer between the femur and the tibia, similar to the components of a TKA (Figure 41). This spacer could help reduce the overall stiffness needed by the collateral ligaments; this would place some of the tibiofemoral contact forces on the spacer so that the collateral ligaments would not need to support as much of the load.

Figure 41: Prosthetic components
Source: http://www.bartonharrismd.com/total-knee-replacement.html

Other improvements to the model include analyzing different shapes of leaf springs and different materials for the leaf springs (only aluminum was analyzed for this research). It is likely that the leaf springs do not need to be rectangular, and SolidWorks simulations could be helpful in determining where the stresses on the springs were located.

5. Conclusions

5.1. Contributions

These realistic knee models were designed to be tested by surgeons in order to collect data on whether or not surgeons can determine the correct knee laxity of the models. This test can determine if relying on a surgeon's feel for determining knee laxity could be the cause for variability in TKAs. If the surgeons cannot determine the laxity of the models, then better training modules or surgical techniques may need to be developed. The models could also be used as a training device for surgeons in order to train surgeons to feel for laxity in the knee before being trained on actual knees.

5.2. Future Work

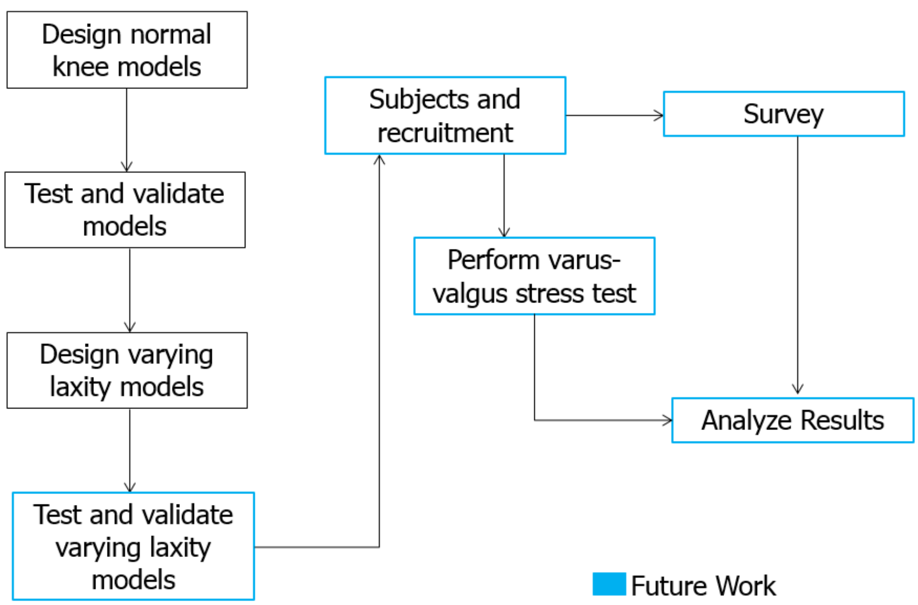


Figure 42: Future work flow

Models of varying laxities still need to be built and validated in order to have surgeons perform the varus-valgus stress test on the models. The complexity of the knee was placed into two collateral ligaments, so there is room for improvement on these models; however, since the normal knee models have already been created and it was shown that varying laxities could be achieved by increasing or decreasing the amount of leaf springs on the prototype, more models can be built using the same methodology. Since the tension springs gave the desired trend, a more exhaustive search can be done to see if there is a better commercially or custom-made spring that fits the design criteria that can mimic a normal knee.

These models can be used to test the surgeons' ability to determine the laxity of the models. Surgeons will be recruited from hospitals in the Greater Columbus area. An IRB was already written so future testing will be expedited. A power analysis was done to determine that a minimum of thirteen surgeons were needed in order to obtain statistical significance. The power analysis used a standard deviation of 3 degrees of difference between varus and valgus excursions [21], a significance level of 0.05, and a power level of 0.9. Surgeons are required to meet inclusion criteria, which includes that all surgeons are orthopedic surgeons (including resident surgeons) that have performed a TKA in the past, and he/she has the ability to perform a varus-valgus stress test. Candidates that are interested in this study will be verified by his/her credentials to ensure that he/she meets the inclusion criteria.

Surgeons will be asked to perform the varus-valgus stress test on the designed knee models. Once the surgeon performs the stress test on the models, the participants will be asked to answer questions about the laxity of the knees. The surgeons will determine if the knee was tight, loose or neither. Participants will also decide which side of the knee (medial or lateral) was tight, loose, or neither. The surgeons will then categorize the knee laxity based on a portion of the Knee Society Score [22] related to mediolateral laxity. Points would be awarded for correct answers based on subcategories (less than 5 degrees, 6-9 degrees, 10-14 degrees, above 15 degrees) within the mediolateral laxity category of the Knee Society score [22]. The participants will also fill out a short survey that included questions about the surgeon's experience. The surveys will ask how many years the surgeon has been practicing, the frequency of TKAs the surgeon has performed, and how many knee replacements the surgeons has performed.

The surgeon's answers will be evaluated in order to determine whether or not the surgeons were able to determine the correct laxity of each of the knee models. The surgeon's answers will also be related to his/her experience using descriptive statistics.

5.3. Summary

This research involved designing a realistic knee model that can be used to test a surgeon's ability to determine knee laxity. This was done by using mechanical concepts to analyze different materials to determine stiffnesses for these materials. The materials were then tested using the stability rig until an accurate prototype was built. This prototype was used to create the final models. If these models were tested on surgeons, this could determine if there is variability in surgeons determining knee laxity. This test could also validate that surgeons can rely on their feel for laxity and variability in TKAs might be coming from a different component of the procedure. If the models suggest that the surgeon's feel is not correctly determining the laxity of the models, then better training modules or devices may need to be developed to decrease the variability of TKAs.

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